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Section 5: 510(k) Summary

1.0 **Submitted By:**

MAR 2 9 2007

Kevin Vu, DDS
2755 S. Nellis #12
Las Vegas, NV 89121
Establishment Registration Number: Pending

Primary Contact:
Glen Feye
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Accurate Consultants, Inc.
1340 West Pennsylvania Ave.
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2.0 **Date Submitted:**

December 20, 2006

3.0 **Device Name(s):**

3.1 **Proprietary Names**

Plaque Scraper-A Interproximal (between teeth) Plaque Remover

3.2 **Classification Name**

21 CFR 872.6650 (Massaging pick or tip for oral hygiene)
Product code - JET (Pick, Massaging).

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4.0 Predicate Devices:

Candidate	Predicate	Manufacturer	Docket Number
Plaque Scraper-A Interproximal (between teeth) Plaque Remover	Reach Stim-U-Dent Plaque Remover	Whitehill Manufacturing, Inc.	K963747

5.0 Intended Use:

The Plaque Scraper-A Interproximal (between teeth) Plaque Remover is an effective cleansing device, which removes plaque and food from between the teeth as part of a program for good oral hygiene to supplement the regular professional care required for oral health. This product is intended for personal oral hygiene use.

6.0 Comparison to Predicate(s):

The following tables show similarities and differences between the predicate identified in Section 4.0 of this summary.

Similarities to the Predicate

Product	Aspect/Characteristic	Comments
Plaque Scraper	Basic Intended Use	Similar to Stim-U-Dent Plaque Remover
	Basic Instructions for Use	
	Provided Non-Sterile	
	Rigid Material	
	Beveled Edge Design	
	Contraindications for Use	

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Differences from the Predicate

Product	Aspect/Characteristic	Comments
Plaque Scraper	Material Composition	The Stim-U-Dent product is a bass wood based product whereas the Plaque Remover is a plastic product.
	Design	The Stim-U-Dent product is a toothpick shaped product with a beveled point on one end whereas the Plaque Remover is designed with an elongated handle for ergonomic convenience and has dual rounded and beveled points on each end.

7.0 Summary of Performance Data:

The information in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to devices already in commercial distribution. Equivalence is demonstrated through intended use, materials and design.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Kevin VU, DDS
C/O Mr. Glen Feye
Accurate Consultants, Incorporated
1340 West Pennsylvania Avenue
San Diego, California 92103

MAR 2 9 2007

Re: K070127
Trade/Device Name: Plaque Scraper-A Interproximal (between teeth) Plaque Remover
Regulation Number: 21 CFR 872.4565
Regulation Name: Dental Hand Instrument
Regulatory Class: I
Product Code: EMN
Dated: March 14, 2007
Received: March 18, 2007

Dear Mr. Feye:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K070127

Section 4: Indications for Use Statements

Indications for Use

510(k) Number (if known): Unknown

Device Name: **Plaque Scraper-A Interproximal (between teeth) Plaque Remover**

Indications for Use:

The Plaque Scraper-A Interproximal (between teeth) Plaque Remover is an effective cleansing device which removes plaque and food between the teeth as part of a program for good oral hygiene to supplement the regular professional care required for oral health. This product is intended for personal oral hygiene use.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K070127

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